

EXHIBIT 1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	Customer Number: 41552
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Lipton, Stuart A., et al.	:	Confirmation Number: 5845
	:	
Application No.: 09/876,187	:	Group Art Unit: 1632
	:	
Filed: June 05, 2001	:	Examiner: Falk, Anne Marie
	:	
For: METHODS OF DIFFERENTIATING AND PROTECTING CELLS BY MODULATING THE P38/MEF2 PATHWAY		

Declaration Pursuant to 37 C.F.R. § 1.132

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Stuart A. Lipton, declare as follows:

1) I am the Stuart A. Lipton who is named as a co-inventor on the above-identified patent application.

2) I understand that the claims stand rejected, in part, as allegedly lacking enablement.

3) Studies have been carried out in my laboratory relating to the neurogenic and antiapoptotic function of MEF2C. A manuscript, which was just recently published in The Journal of Neuroscience, describing these studies is attached as Exhibit A.

4) The attached manuscript describes the generation of stably transformed murine embryonic stem (ES) cells that express a constitutively active form of myocyte enhancer factor 2C (MEF2CA). The results show that expression of MEF2CA, both *in vitro* and *in vivo*, under regulation of the nestin enhancer effectively produces “neuronal” progenitor cells that differentiate into a virtually pure population of neurons. Histological, electrophysiological, and

behavioral analyses demonstrate that MEF2C-directed neuronal progenitor cells transplanted into a mouse model of cerebral ischemia can successfully differentiate into functioning neurons and ameliorate stroke-induced and potentially other neurodegenerative disease-associated behavioral deficits.

5) Studies have also been carried out in my laboratory relating to the effect of MEF2C expression in human embryonic stem cells on neurogenesis. These data are attached as Exhibit B.

6) The attached data show that expression of MEF2CA in human embryonic stem cells positively regulates neurogenesis.

7) In conclusion, these results show the expression of MEF2CA in mouse and human embryonic stem cells and differentiation into neuronal cells.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that any such willful false statement may jeopardize the validity of the application or any patent issued thereon.

_____/Stuart A. Lipton/
Date 25 August 2008 Stuart A. Lipton, M.D., Ph.D.